By Senator Fasano

11-00369C-12 20121310__

A bill to be entitled

An act relating to pharmacy audits; providing purpose; providing definitions; providing standards and procedures regulating the auditing of pharmacy records conducted on behalf of a pharmacy benefit manager; providing contract requirements and limitations; providing for the delivery of and response to preliminary and final audit reports; providing for the appeal of audits; providing penalties and remedies; providing for applicability; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Auditing of pharmacy records.—

(1) PURPOSE.—The purpose of this section is to establish standards for the audit of pharmacy records conducted by or on behalf of a pharmacy benefit manager or other entity listed in paragraph (2)(b).

(2) DEFINITIONS.—As used in this section, the term:

(a) "Audit" means a formal review of the records of a pharmacy by an entity that finances or reimburses the cost of health services or pharmaceutical products.

(b) "Entity" means a pharmacy benefit manager, a managed care company, a health plan sponsor, an insurance company, a third-party payor, a state agency, or any company, group, or agent that represents or is engaged by such entities.

(c) "Pharmacy benefit manager" means a person, business, or other entity that performs pharmacy benefit management or

performs pharmacy benefit management on behalf of a pharmacy benefit manager through a contractual or employment relationship.

(d) "Pharmacy benefit management" means the provision of administrative services related to processing prescription claims for pharmacy benefit and coverage programs. Such services may include contracting with a network of pharmacies; audit compliance; establishing payment levels for provider pharmacies; negotiating rebate arrangements; and developing and managing formularies, preferred drug lists, and prior authorization programs.

(3) AUDITING STANDARDS AND PROCEDURES.—An entity conducting an audit of pharmacy records must adhere to the following standards and procedures:

(a) The same standards and parameters must be used to audit all pharmacies.

(b) An audit that involves clinical or professional judgment must be conducted by, or in consultation with, a pharmacist licensed in this state.

(c) An auditing entity conducting an onsite audit must give the pharmacy at least 30 days' written notice before conducting the audit. Such notice must identify the prescription numbers to be audited.

(d) The audit may not take place during the first 7 days of the month unless otherwise consented to by the pharmacy.

(e) The period covered by the audit may not exceed 12 months, unless superseded by federal law.

(f) The initial audit may not include more than 1 percent of the average monthly prescription claims, not to exceed 200

prescription claims. However, the auditing entity may conduct further audits of prescription claims that have substantiated and documented discrepancies.

(g) The pharmacy may use the records, or copies of records, of a hospital, physician, or other authorized practitioner to validate the pharmacy record.

(h) Any prescription that complies with state law and rule requirements may be used to validate claims in connection with prescriptions, refills, or changes in prescriptions.

(i) Calculations of overpayments may not include dispensing fees.

(j) Interest may not accrue during the audit period.

(k) If an audit results in the identification of any clerical or recordkeeping errors, such as typographical errors, scrivener's errors, or computer errors, in a required document or record, the pharmacy is not subject to recoupment of funds by the pharmacy benefit manager unless the pharmacy benefit manager can provide proof of intent to commit fraud or such error results in actual financial harm to the pharmacy benefit manager, a health plan managed by a pharmacy benefit manager, or a consumer.

(l) The auditing entity must allow the pharmacy to resubmit claims disputed by the audit using any commercially reasonable method, including, but not limited to, faxing, mailing, or electronic submission.

(m) An exit interview that provides a pharmacy with an opportunity to respond to questions and comment on and clarify findings must be conducted at the end of an audit. The time of the interview must be agreed to by the pharmacy.

(n) The auditing entity may not collect disputed funds until the audit process, including appeals, is complete.

(o) The auditing company or agent may not receive payment based on a percentage of the amount recovered.

(p) If not superseded by state or federal law, audit information may not be shared and is confidential. Auditors shall have access only to previous audit reports on a particular pharmacy conducted by the same auditing entity.

(4) CONTRACT REQUIREMENTS.—

(a) Each pharmacy network provider contract must provide:

1. The methodology and resources used for calculating the maximum allowable cost (MAC) pricing of the pharmacy benefit manager;

2. For updating pricing information at least weekly; and

3. A process for promptly notifying network pharmacies of pricing updates.

(b) The pharmacy network provider contract may not include a provision that allows the use of extrapolation in calculating the recoupment or penalties for audits, unless agreed to by both parties.

(c) A pharmacy benefit manager may not automatically enroll a pharmacy in a contract or modify an existing contract without written agreement from an authorized representative of the pharmacy.

(d) Unless required by federal law, a contract entered into or renewed on or after July 1, 2012, may not contain auditing standards, procedures, contract requirements, appeal procedures, or reporting requirements that are more restrictive than those contained in this section.

(5) AUDIT APPEALS.—

(a) The auditing entity must establish a written process for appealing preliminary and final audit reports. The process must include an option that offers the pharmacy a final appeal to the health plan sponsor. If the pharmacy or pharmacy benefit manager is not satisfied with an appeal, that party may seek mediation.

(b) If unsubstantiated audit discrepancies are discovered following the appeal, they shall be dismissed without further proceeding.

(6) AUDIT REPORTS.—

(a) A preliminary audit report must be delivered to the pharmacy, or its corporate office of record, within 60 days after the conclusion of the audit.

(b) A pharmacy shall have at least 30 days following receipt of the preliminary audit to provide documentation to address any discrepancy found in the audit.

(c) A final audit report must be delivered to the pharmacy, or its corporate office of record, within 120 days after receipt of the preliminary audit report or final appeal, whichever occurs later.

(d) Chargebacks, recoupment, or other penalties may not be assessed until the appeal process has been exhausted and the final report issued.

(e) The auditing entity must also provide a copy of the final report, including the disclosure of any money recouped in the audit, to the plan sponsor.

(7) PENALTIES AND REMEDIES.—Any person injured as a result of a violation of this section may bring a civil action against

the person, corporation, or business entity violating this section for the recovery of all actual damages occurring as a result thereof.

(8) APPLICABILITY.—

(a) This section applies to contracts entered into, amended, extended, or renewed on or after July 1, 2012.

(b) This section does not apply to:

1. Audits of Medicaid-related pharmacy records conducted pursuant to s. 465.188, Florida Statutes.

2. Any investigative audit that involves fraud or willful misrepresentation.

Section 2. This act shall take effect July 1, 2012.